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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Neuberger et al.

SERIAL NO. : 09/827,666 EXAMINER : Brian S. Kwon

FILED : April 6, 2001 ART UNIT : 1614

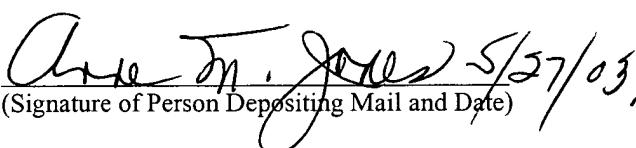
FOR : COMPOSITIONS AND METHODS FOR PROMOTING TISSUE
REGENERATION

Certificate of Mailing Under 37 CFR 1.8

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Anne M. Jones

(Name of Person Depositing Mail)


(Signature of Person Depositing Mail and Date)

RESPONSE TO COMMUNICATION FOR NON-RESPONSIVE ELECTION TO
REQUIREMENT FOR RESTRICTION
UNDER 35 U.S.C. §121

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

Dear Sir:

Responsive to the Office Action dated April 25, 2003, issued in connection with the above-identified Application, which is now due for response on May 27, 2003, by virtue of the fact that May 25, 2003 was a Sunday, and May 26, 2003 was a holiday, please consider the following remarks.

REMARKS

By this Office Action, the Examiner alleges that the response filed on August 12, 2002 was not fully responsive to the prior Office Action. Thus, a complete response to the Requirement for Restriction is required.

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

Group I. Claims 1-36 and 43-66, drawn to a method of use with a composition comprising a compound represented by formula (I) or (II)

Group II. Claims 37-38, drawn to a composition comprising a compound represented by formula (I) or (II)

Group III. Claims 39-40, drawn to a composition comprising one or more cells

Furthermore, it has been noted that if Group I is elected, further restriction is required among the following groups:

Ia: Claims 1-18, 32-36 and 57-58, drawn to a method for promoting tissue regeneration with a composition containing compound represented by formula (I)

Ib: Claims 19-28 and 46-56, drawn to a method for promoting increased neuronal function after a decrease in neuronal function due to a trauma, an injury or a neurodegenerative disease or condition with a composition containing compound represented by formula (I)

Ic: Claims 29-31, drawn to a method for improving learning or memory function with a composition containing compound represented by formula (I)

Id: Claims 43-45, drawn to a method for promoting the proliferation or differentiation of progenitor cells with a composition containing compound represented by formula (I)

Ie: Claims 59-63, drawn to a method for treating liver disease or condition with a composition containing compound represented by formula (I)

If: Claims 64-66, drawn to a method for growing cells in vitro or in vivo with a composition containing compound represented by formula (I)

Ig: Claims 1-18, 32-36 and 57-58, drawn to a method for promoting tissue regeneration with a composition containing compound represented by formula (II)

Ih: Claims 19-28 and 46-56, drawn to a method for promoting increased neuronal function after a decrease in neuronal function due to a trauma, an injury or a neurodegenerative disease or condition with a composition containing compound represented by formula (II)

Ii: Claims 29-31, drawn to a method for improving learning or memory function with a composition containing compound represented by formula (II)

Ij: Claims 43-45, drawn to a method for promoting the proliferation or differentiation of progenitor cells with a composition containing compound represented by formula (II)

Ik: Claims 59-63, drawn to a method for treating liver disease or condition with a composition containing compound represented by formula (II)

Il: Claims 64-66, drawn to a method for growing cells in vitro or in vivo with a composition containing compound represented by formula (II)

Furthermore, if Group II is elected, further restriction is required as follows:

IIa: Claims 37-38, drawn to a composition comprising a compound represented by the formula (I)

IIb: Claims 37-38, drawn to a composition comprising a compound represented by the formula (II)

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group I, claims 1-36 and 43-66, drawn to a method of use with a composition comprising a compound represented by formula (I) or (II), with traverse. With respect to the further requirement for restriction, Applicants elect to prosecute the invention of Group I-g, claims 1-18, 32-36 and 57-58, which are drawn to a method for promoting tissue regeneration with a composition containing a compound represented by formula (II), with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Claims 1-18, 32-36 and 57-58 of Group Ig are drawn to methods for promoting tissue regeneration with a composition containing compound represented by formula II, that are fundamentally related to Claims 19-28 and 46-56 of Group Ih, drawn to methods for promoting increased neuronal function after a decrease in neuronal function due to a trauma, an injury or a neurodegenerative disease or condition with a composition containing compound represented by formula II. Applicants respectfully assert that the search for any of the methods separately classified by the Examiner as the invention of Group Ig would require an additional search of the identical classes wherein the invention of Group Ih are classified, thus resulting in a duplicate search for the same material. Applicants respectfully draw the Examiner's attention to the fact that several of the claims dependent from claim 1, which Applicant has elected by virtue of the claim falling within the elected Group Ig, are drawn to the tissue regeneration aspect being of neuronal origin, ie. claims 8, 10, 12. Thus, a search on the claims elected by way of the response to the restriction requirement would require a search on neural tissue regeneration. Applicants assert that such a search would result in identification of identical subject matter covered in claims 19 through 28 and 46 through 56, which read on methods for treating injury to neural tissue and methods of treating neurodegenerative diseases, since one primary aspect of the methods and compositions of the present invention are directed to the use of neural regenerative therapy as a means for repair of neural tissue and treatment of neurodegenerative diseases. Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Group Ig with Group Ih can be made without serious burden, and therefore the Examiner must examine all of the claims, or in the alternative, at least those of Groups Ig and Ih, of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group Ig and Group Ih is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,

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